

MAR 24 2003

3. DISCUSSION OF SAFETY AND EFFECTIVENESS

A. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

Model No./Name: NMA 1052 Console with NMA 100 Laser Accessory

Classification: Lamp Non-heating – Section B – NHN
Physical Medicine Device, 21 CFR 89.5500 (Class II)

Predicate Device: MedX LCS Laser Series – K021985

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

B. DEVICE SPECIFICATIONS

NMA 100 Laser Accessory primarily consists of a hand held laser cluster accessory powered by the NMA 1052 Console. The hand held laser cluster contains the laser diodes and assembly, circuit board, electronics and labels. The hand piece is controlled from the console. The console automatically times the 33-second cycles of treatment.

The NMA 100 Laser Accessory is an 830 nm infrared laser indicated for adjunctive use in the temporary management of hand and wrist pain associated with carpal tunnel syndrome. The NMA 100 Laser utilizes three semiconductor laser diodes each emitting approximately 30 milliwatts (maximum 35 mW) continuous wave light at 830 nm. It utilizes 830 nm gallium-aluminum-arsenide laser diodes. The console automatically turns itself off after three joules of energy has been delivered.

The device meets the requirements of the UL2606 standards in United States.

The product has been:

- Health Canada – Medical Therapeutic Device approved (Canada)
- UL Entela field evaluated and labeled (file FE-32134-1)
- Underwriters Laboratories of Canada field evaluated (file FE:32505-2)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Anita Saltmarche, RN, BScN, MHSc
Vice President of Clinical and Scientific Affairs
MedX Electronics, Inc.
3535 Laird Road, Unit 2
Mississauga, Ontario
Canada L5L 5Y7

MAR 24 2003

Re: K024310

Trade/Device Name: MBM 1010 Console System and LCT 101 Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, non-heating, for adjunctive use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: December 17, 2002
Received: December 24, 2002

Dear Ms. Saltmarche:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Prorost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1510(k) Number (if known): K024310Device Name: MBM 1010 and LCT 101

Indications For Use:

The LCT 101 low level laser accessory is a non-heating infrared lamp powered by the MBM 1010 console, as per 21 CFR 890.550. It emits energy in the infrared spectrum, with an auxiliary visible red guide light. It is indicated for adjunctive use in the temporary relief of the hand and wrist pain associated with carpal tunnel syndrome.

Miriam C. Provost(Division Sign-Off)
Division of General, Restorative
and Neurological Devices510(k) Number K024310

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)